REMARKS

This Amendment is being submitted in conjunction with a Request for Continued Examination (filed concurrently herewith) in response to the Official Action dated 27 February 2006. Claims 1, 8 and 15 are amended, and claim 2 is canceled herein. Thus, claims 1, 3-15, 17-19, 21 and 22 remain pending.

The Examiner rejected Claims 1-15, 17-19 and 21-22 under 35 U.S.C. 112, first paragraph, because the Amendment submitted 20 December 2005 introduced a "stepping precision pump" into the claims whereas the specification, as originally filed, describes a "precision fluid pump" or a "precision pump" (pages 6-7 and 11 of the specification). The Examiner contends that a stepping precision pump constitutes new matter. Applicant agrees that a "stepper" pump was not explicitly identified as such, but would be a known expedient to accomplish the requisite configuration as described. Note at paragraph [0023] that "the pump system should be capable of making precise micro-displacements of at least 0.5 micron resolution to obtain maximum accuracy....The fluid is generally moved to the capillary tube in discrete movements that are usually synchronized to an optical detection system and the cell gating system..." At paragraph [27] "When a selected cell is in position in the capillary, the control electronics either applies the external magnetic field, or not, depending upon which exit port is desired. Once the magnetic field is removed (if it had been applied), the gate re-aligns itself to the normal position or non-selected (waste) port. [29] [the] "system that can move a cell

into position to be identified, identify it and make a sort decision, move the selected cell to the control gate (if not already in position), set the control gate, and pull the selected cell out into a proper exit port. The present invention can be run in a pulsed (or discrete motion) mode.." The foregoing is essential because the present system is unique in its ability to move a cell in position before the gate, stop it for inspection, and direct it to the proper exit port based on the optical inspection. This requires a pump capable of discrete micro-displacements of at least 0.5 micron resolution. Notwithstanding the foregoing support, claim 1 is herein amended to delete the "stepping" and recite instead a *pulsed-mode precision microdisplacement pump.* Claims 8 and 15 are similarly amended.

The Examiner rejected claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Examiner, on line 3 of claim 21, the phrase "said selected cell" lacks antecedent basis. This has been changed to -said desired cell- as suggested.

The Examiner rejected claims 1-15 and 21-22 under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al.

U.S. Patent No. 5,837,200 to Diessel et al discloses a continuous-flow sorting device for cells or viruses in liquids. The sorting apparatus is provided with a feed inlet for the biological liquid which branches into a microstructured system of multi-parallel main channels and sorting

modules each with a switch unit for distribution to two different outlet channels. Inside a sorting module at least one sensor is arranged on each main channel, and a sorting actuator controlled by the relevant sensor is arranged on each switch unit. Diessel fleetingly suggests that the sorting actuator can be magnetostrictive. The flow through the channels is continuous, and the Examiner acknowledges that Diessel et al. fails to teach of a precision pump and vacuum for causing the cell stream to flow through the channels, or any optical detection system comprise a photomultiplier or a diode array. According to the Examiner, Wada et al (20030027225) adds a positive displacement pump, peristaltic pump or another type of common pump, or vacuum source, plus an optical detection system located along the length of the main channel serves to detect and analyze cells flowing there through. The optical detection system can measure light scattering or fluorescence by means of a photodiode or a photomultiplier. The Examiner contends that it would have been obvious to use a precision pump or a vacuum as in Wada to move the cell-containing fluid through the channels in the device of Diessel et al, and that it also would have been obvious to use one or more diodes or photomultipliers as the optical detection system in the device taught by Diessel et al.

The present cell sorter is fundamentally different in that it employs a pulsed-mode precision microdisplacement pump capable of making precise micro-displacements of at least 0.5 micron resolution to position the desired cells at a predetermined position in view of the optical detection system, detect the characteristics of the cell while stopped, make a sort decision, and

then apply the external magnetic field to the magnetostrictive actuator depending upon which exit port is desired. To do this the pump is run in a pulsed (or discrete motion) mode, and is synchronized both to the optical detection system and the magnetostrictive actuator. This is an essential feature of the present invention because a much more accurate optical (spectroscopic) examination can be made when the cell is stopped in position before a detection window. In the present publication at [at 0026] "When either a fluorescence or light scatter signal (or both) indicates a cell to be sorted is in position, the pump control electronics keeps track of the time shift necessary so that the cells are properly presented to the gating mechanism. The gating mechanism can be exercised when the selected *cell is in exactly the correct position*. Claim 1 is herein amended to require a "*pulsed-mode precision microdisplacement pump* causing fluid containing desired cells to enter said inlet port *and stopping fluid flow when a particular cell is at a predetermined position*", plus "a control unit *connected to said pump, said cell detection system and said sorting gate for synchronizing discrete fluid microdisplacements by said pump with said cell detection system and magnetostrictive actuator of said sorting gate*". Claims 8 and 15 are amended in the same respect.

Diessel et al. shows only a continuous flow cell sorter with magnetostrictive switches, and does not teach or suggest a pulsed-mode precision microdisplacement pump for stopping fluid flow when a particular cell is at a predetermined position and fails to teach or suggest discrete (pulse mode) operation at all, let alone the structure to accomplish it, including a cell

detection system operative at the stopped position to see if the cell is a desired cell. Moreover, Diessel et al. does not suggest a control unit connected to the pump, cell detection system and sorting gate for synchronizing discrete fluid microdisplacements by said pump with said cell detection system and magnetostrictive actuator. Wada et al. only add a range of pump types and vacuum sources to a fluid transport system, and suggests stopping his pump, but he still does not teach or suggest a pulsed-mode precision microdisplacement pump as recited above, nor any of the other structural or functional limitations described above and recited in claims 1, 8 or 15. Neither of these references teach or suggest synchronizing both a magnetostrictive gate and an optical detection system with a pulsed-mode precision microdisplacement pump, or stopping fluid flow when a particular cell is at a predetermined position for the cell detection. Claims 1, 8 and 15 require these elements and are patentably distinguished.

Even if all the elements could be found in these two references, in order to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." Also, it is well settled that an inventive combination cannot be anticipated by finding individual features separately in the prior art and combining them in a piecemeal manner to show obviousness. See In re Kamm and Young , 17 USPQ 298, affd. (Court held that "The rejection here runs afoul of a basic mandate inherent in section 103 - that a piecemeal reconstruction of the prior art patents in the light of appellants disclosure shall not be

the basis for a holding of obviousness). Because the Examiner is improperly piecing together a precision pump, magnetistrictive gate, and optical detection system from separate prior art references, the combination is improper, and thus the Examiner has failed to make a prima facie case of obviousness.

Claims 17-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al as applied to claims 1-15 and 21-22 above, and further in view of Clark. According to the Examiner Clark teaches a magnetostrictive rod 12 disposed within a fluid flow channel 10. The rod is initially in close fitment with a discharge port 14 to restrain the flow of fluids through the port 14. The Examiner submits that use of a magnetostrictive rod as in Clark would be an obvious substitution for the magnetostrictive sorting actuator in Diessel et al. Applicant disagrees. As stated above, the present invention includes a fluid (and cell) control system by which a pulsed-mode precision microdisplacement pump is synchronized to a magnetostrictive gate and an optical detection system for stopping fluid flow when a particular cell is at a predetermined position for the cell detection, and gating in accordance with the detection. Neither Diessel et al nor Wada et al as discussed above suggest this system, and Clark only adds a magnetostrictive rod. Not only does Clark fail to bridge the gap, but it would be completely unobvious to one trying to implement the rod of Clark in the hybrid system of Diessel et al. and Wada et al. exactly how to control the rods to perform a gating function in sunchronism to the fluid flow and detection. Claims 17-18 are patentably distinguished.

Claim 19 was rejected under 35 U.S.C. 103(a) as being unpatentable over Diessel et al in view of Wada et al as applied to claims l-15 and 21-22 above, and further in view of Kamentsky. The Examiner contends that Diessel et al fail to teach optical fibers for conveying light from a source into the main channel, but that Kamentsky does show this in a similar context. However, claim 19 depends from claim 15 which is a method claim requiring the steps of causing said fluid to pass through an optical detection region..., stopping said stepping precision pump when said particular desired cell is in a predetermined position...applying a magnetic field to a magnetostrictive gate...pulsing said stepping precision pump to cause said particular desired cell to pass through said cell exit port...removing said magnetic field from said magnetostrictive gate...and drawing said particular desired cell from said exit port. Neither Diessel et al or Kamentsky et al teach or suggest this particular sequence of method steps and claim 19 is patentably distinguished.

In view of the above, all pending claims 1, 3-15, 17-19, 21 and 22 are believed to avoid all the objections/rejections set forth in the Official Action. The case should be in allowance. A Notice to this effect is respectfully requested, and the Examiner is invited to call the undersigned at 410.419.6899 to discuss any remaining issues.

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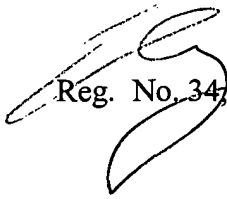
Respectfully submitted,



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